

### REMARKS

In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 12 - 23, 25 - 34 and 36 - 45 stand rejected under 35 U.S.C. § 103 as obvious over Walker (U.S. Patent No. 5,755,693) in view of Deem (U.S. Patent No. 5,104,389). The Examiner has maintained his assertion that Walker shows a device as claimed except for the element that none of the slits extends in width to the inner surface of the sheath, but that Deem shows such a device.

Claim 13 recites an apparatus for facilitating insertion of a flexible medical device into a body lumen comprising an elongated body portion and a valve including foam material filling at least some of the length of a passageway of the elongated body portion, wherein a "length of the foam material [of the valve] within the passageway being greater than the width of the foam material at any point within the passageway." The valve is also recited as including "one or more self-sealing slits wherein none of the slits in the foam material, none of the slits extending in width to the inner surface of the sheath." Claims 26 and 39 recite similar claim elements and, it is respectfully submitted, are allowable for the same reasons.

The Examiner has agreed that Walker shows no such slits and it is respectfully submitted that Deem also includes no disclosure of a valve with slits that do not extend to an inner surface of the sheath as contended by the Examiner. The only

discussion of the extent of the slits through the foam of Deem is in regard to the longitudinal direction (in regard to partition member 24). This is the only embodiment described as including a slit that does not pass all the way through the foam. There is no reference to the extent of any of these slits in the transverse direction. Specifically, col. 6, lines 1 - 7 of the specification state that Figs. 3 and 4 show opposed sides (opposed longitudinally) of the partition member 24 where the slit 40 does not extend all the way therethrough.

The Examiner responded to this argument by stating that Walker shows slits not extending to an inner surface of the sheath in (Fig. 8, ref. 32) (8/26/03 Office Action, page 4, para. 4). However, this is clearly contradicted by the Examiner's own assertion on page 2 of the same Office Action that Walker fails to disclose one or more self-sealing slits "wherein none of the slits extend in width to the inner surface of the sheath." (Id., page 2, para. 2). The Examiner stated, as grounds for the rejection that Walker failed to show this very element and supplied Deem as an additional reference to make up this deficiency. However, it is respectfully submitted that the response to the Applicant's arguments concedes that Deem fails to cure the deficiency. Similarly, in the Office Action mailed April 23, 2003, the Examiner stated that Walker fails to disclose "wherein none of the slits extend in width to the inner surface of the sheath."

In any case, it is respectfully submitted that even Fig. 8 of Walker fails to show this claim element. Claim 13 does not require that all slits penetrate through the foam to the sheath. Rather, this claim recites that "none of the slits [extends] in width to the inner surface of the sheath." Thus,

although reference numeral 32 does show slits that do not penetrate through this foam to the sheath, there is a large slit between the semi-circular halves of the valve 30C which extends across the entire diameter of the valve.

Furthermore, the Examiner has pointed to Fig. 9 and col. 7, lines 37 - 43 as showing a valve wherein a "length of the foam material [of the valve] within the passageway [is] greater than the width of the foam material at any point within the passageway," as recited in claim 13. However, it is respectfully submitted that these lines make no mention of a relationship between a longitudinal length of the foam and its width. In fact, this portion of Walker simply states that the valve of Fig. 9 is longer longitudinally than the valve shown in Fig. 6.

In addition, the Examiner has pointed to Fig. 1 and the corresponding description in col. 5, lines 6 - 14 of Deem as showing the recited relation between the longitudinal length and width of the valve. However, it is respectfully submitted that this description refers to the length and width of element 27 which is simply a foamed elastomer material with no slits extending therethrough. Specifically, Deem shows a valve including a first, solid, hydrophilic elastomer wall bonded to a foamed elastomer. The foam portion 27 of the valve of Deem includes no slits extending therethrough. Thus, it is respectfully submitted that Deem does not show a valve including a foam material filling at least a portion of the length of a passageway with "one or more self sealing slits in the foam material," as recited in claim 13. Specifically, Deem states that, if desired, the *partition member* may define a reclosable aperture such as a slit to further facilitate penetration of the elongated member through the partition member. However, no slits

are described or suggested in any foam material.

Thus, it is respectfully submitted that neither Walker nor Deem shows a valve comprised of foam filling at least a portion of the length of a passageway with "a length of the foam in the passageway being greater than a width of the foam material at any point within the passageway" in combination with "one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath," as recited in claim 13.

It is therefore respectfully submitted that claim 13 is not rendered obvious by Walker and Deem either taken alone or in combination and that this rejection should be withdrawn.

In addition, as stated previously there is ample legal authority for the proposition that the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). Put another way, *it is improper to modify a prior art reference unless the prior art suggests the desirability of the specific modification.* In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947

F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

As described above, Deem shows no slits in any foam material and therefore provides absolutely no motivation to one of skill in the art to alter the design of slits in the foam of Walker. The Examiner agrees that the rejection was based on hindsight, but states that this hindsight reconstruction of the invention is proper because it takes into account only knowledge which was within the level of ordinary skill in the art at the time. However, the Examiner gives no specific indication of what knowledge he is assuming for those of skill in the art, nor does he indicate how any such knowledge makes this hindsight reconstruction allowable. The Examiner goes on to state further cases in support of the proposition that it is proper to take into account inferences ones skilled in the art would have drawn from the cited references. However, the Examiner likewise fails to show any specific instance of an application of this rule. Thus, it is respectfully submitted that this rejection is based on an improper hindsight reconstruction of the invention as well as vague and unsupported statements about the meaning of the references to those skilled in the art which are used to prop up deficiencies in the references with respect to various claim elements.

Furthermore, as stated previously, it is respectfully submitted that all of the embodiments of Walker are shown with at least one slit that does extend through the entire width of the foam valve because this feature aids in the splitting of the

sheath and its removal from the catheter while leaving the catheter in place within the body. Thus, without specific motivation for a change to a fundamental feature of the invention, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to depart from the teaching of Walker and would not have drawn the inferences hinted at by the Examiner.

For these reasons it is respectfully submitted that claims 13 along with claims 26 and 39 are not rendered obvious by Walker and Deem either taken alone or in combination and that this rejection should be withdrawn. Because claims 12, 14 - 23, 25, 27 - 34, 36 - 38 and 40 - 45 depend from and, therefore, include all of the limitations of one of claims 13, 26 and 39, it is submitted that these claims are also allowable.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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